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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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William P. Van Antwerp

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/035,831	Applicant(s) VAN ANTWERP ET AL.	
	Examiner Laura A. Bouchelle	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,9-27,68,69 and 87-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,9-27,68,69 and 87-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/8/06, 1/14/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 7 and 25 are objected to because of the following informalities: Claims 7 and 25 depend from cancelled claim 6. Appropriate correction is required.
2. Claim 96 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 96 is identical to claim 90.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1, 9-16, 68, 87, 88, 89, 91, 92, 93, 95, 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al (US 4994047) in view of Bobo, Sr. (US 5573007). Walker discloses a multi-layer catheter comprising tubing comprising at least one layer, wherein one layer includes a hydrophilic material that reduces the diffusion of molecules through the tubing (See Abstract). Walker discloses that the catheter can have two or three layers (Col. 12, lines 53-60). The hydrophilic layer is essentially polyurethane (Col. 4, lines 67-68) and can be either the inner layer or the outer layer (Col. 3, lines 4-7).

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5. Claims 1 and 10 differ from Walker in calling for the layer to comprise saran. Claim 68 differs in calling for a material that reduced the diffusion of small molecules. Bobo teaches a catheter comprising a layer of saran that serves to minimize gas or liquid permeability and prevent migration of matter through the tubing (Col. 8, lines 11-19). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Walker to include a layer of saran as taught by Bobo to minimize gas or liquid permeability and prevent migration of matter through the tubing.

6. Claim 15 differs from Walker in view of Bobo in calling for the outer layer to be silicone. At the time the invention was made, it would have been an obvious matter of design choice to form the outer layer from a variety of materials as disclosed by applicant. Applicant has not disclosed that having an outer layer of silicone serves any advantage or particular purpose or solves a stated problem. Furthermore, one of ordinary skill would expect Walker in view of Bobo and applicant's invention to perform equally well with the materials disclosed by Walker or with silicone because many different materials can have similar characteristics to silicone. Therefore, it would have been prima facie obvious to modify the device of Walker in view of Bobo to include a silicone outer layer to obtain the invention as specified in claim 15 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art.

7. Claims 87, 88, 93, 94 are understood to be Product by Process recitations. Claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The

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patentability of a product does not depend on its method of production. See MPEP 2113.

Therefore, claims 87 and 88 are not patentably over the prior art.

8. Claims 2 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker in view of Bobo as applied to claims 1 and 68 above, and further in view of Ash et al (US 6042561). Claims 2 and 69 differ from Walker in view of Bobo in calling for the insulin formulation to be maintained in the tubing. Ash teaches an infusion device comprising a continuous insulin infusion pump wherein the insulin is maintained in the tubing since the delivery is continuous (Col. 1, line 63 – Col. 2, line 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Walker in view of Bobo to maintain the insulin formulation in the tube as taught by Ash to prevent occlusions or deposits from forming in the tubing.

9. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Bobo in view of Ash et al as applied to claim 2 above, and further in view of Brange et al (US 4472385). Claim 4 differs from the teachings above in calling for the insulin to be a high concentration formulation. Claim 5 calls for the formulation to be greater than about 100 U/ml. Brange teaches a stabilized insulin preparation comprising a high concentration formulation of insulin at a concentration of 40 to 1000 U/ml (Col. 3, lines 50-52). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the insulin formulation of Walker in view of Bobo in view of Ash to be of a concentration greater than about 100 U/ml as taught by Brange to achieve the optimal concentration.

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10. Claims 3, 17, 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Bobo as applied to claim 1 above, and further in view of Brange et al (US 4472385). Claim 3 differs from Walker in view of Bobo in calling for the insulin formulation to be stabilized by being substantially free of deposits or occlusions comprising insulin and an excipient. Brange teaches a stabilized insulin preparation comprising highly purified insulin and an excipient to provide the maximum concentration and stability (Col. 3, lines 45-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include in the device of Walker in view of Bobo the insulin formulation of Brange so that the insulin has maximum stability.

11. Claims 17 and 18 call for the small molecules to be charged or not charged and the charged molecules to include metal ions. Brange teaches that the molecules contain magnesium ions to stabilize the insulin (Col. 3, lines 21-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include in the device of Walker in view of Bobo the metal ions of Brange to stabilize the insulin.

12. Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view Bobo in view of Brange as applied to claim 17 above, and further in view of Nelson (US 5702372). Claims 19- 24 differ from the teachings above in calling for the stabilizing catheter to reduce the flow of carbon dioxide or phenols into the tubing. Nelson teaches a lined infusion catheter comprising a liner made of Teflon that is relatively nonporous to prevent contaminants such as carbon dioxide from diffusing into the lumen and denaturing the insulin (Col. 4, lines 9-

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15). Adjusting the porosity and thickness of the liner is inherently capable of reducing the diffusion of contaminants any amount. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Walker in view Bobo in view of Brange to reduce the diffusion of carbon dioxide or phenol into the lumen as taught by Nelson to prevent the insulin from denaturing.

13. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Bobo as applied to claim 1 above, and further in view of Ekwuribe et al (US 6309633). Claims 26 and 27 differ from Walker in view of Bobo in calling for the protein to be the insulin analogue Lispro. Ekwuribe teaches the use of the insulin analogue Lispro in the place of insulin because Lispro has a more precise action profile than human insulin (Col. 14, lines 7-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Walker in view of Bobo to have Lispro as taught by Ekwuribe because Lispro has a more precise action profile than human insulin.

14. Claim 90 rejected under 35 U.S.C. 103(a) as being unpatentable over Walker in view of Bobo as applied to claim 68 above, and further in view of Van Antwerp et al (US 6443942). Claim 90 differs from the teachings above in calling for the protein compatible material to contain a PEG moiety. Van Antwerp teaches a medication device with protein stabilizing surface coating wherein the coating includes a PEG moiety that promotes the maintenance of the specific protein's native state (Col. 6, lines 55-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Walker in view of

Bobo to include a layer containing PEG moiety as taught by Van Antwerp to promotes the maintenance of the specific protein's native state.

Response to Arguments

15. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
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